



JAN - 4 2005

WARNING LETTER

VIA OVERNIGHT DELIVERY

Thomas Snee
IONETICS
9991 Goodhue STREET
Blaine, MN 55449

Dear Mr. Snee:

This is to advise you that the Food and Drug Administration (FDA) has reviewed labeling for your product "Angioprim," including promotional flyers shipped with product orders and Internet labeling from your web sites at <http://www.angiocure.com>, <http://www.angioprim.com>, and <http://www.youticker.com>. Based on this labeling, FDA has determined that Angioprim is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims in your product labeling establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web sites include:

Angioprim.com

- "Angioprim is the most effective method to clean blocked arteries without surgery, needles or hazardous drugs."
- "If you have any of the following, Angioprim can also be of help: Alzheimer's, Angina, Bone Spurs... Cardiovascular Disease ... Congestive Heart Failure, Diabetes, Erectile Dysfunction, Gallbladder Disease, Kidney Stones, Lupus, Osteoarthritis, Osteoporosis, Parkinson's, Rheumatoid Arthritis, Scleroderma, Senile Dementia"
- "Angioprim is a true way to reverse Cardiovascular disease and reverses many of the symptoms of Arthritis, Osteoporosis, Alzheimer's, Parkinson's and Diabetes"
- "The ingredient in Angioprim has been proven to ... benefit those with Rheumatoid Arthritis, Lupus, Scleroderma, Senile Dementia, Alzheimer's and Parkinson disease along with other immune disorders."
- "Angioprim Provides Significant Benefits For: Angina, cardiovascular disease, to prevent strokes and provide noticeable relief for: Osteoarthritis, Gallstones, Kidney stones ... and can reduce insulin usage for Diabetics."

Anginacure.com and Yourticker.com

- “Heart Disease is Reversible Without Surgery ... Angioprim ... The most effective way to unplug blocked arteries.”
- “Angioprim is the most effective way to reverse heart disease, control arthritis & kidney disease and improve health for those with Diabetes, Alzheimer’s and Osteoporosis.”
- “Angioprim provides noticeable relief for: Osteoarthritis, Gallstones, Kidney stones ... and can reduce insulin usage for Diabetics.”
- “The ingredients in Angioprim has [sic] been proven to ... benefit those with Alzheimer’s and Parkinson disease, Rheumatoid Arthritis, Lupus, Scleroderma, Senile Dementia, along with other immune disorders.”

All three sites

- “Angioprim will reduce plaque and restore circulation to blocked veins and arteries.”
- “Angioprim binds to unwanted calcium and dissolves arterial plaque.”
- “Angioprim stimulates the enlargement of small vessels, so that they allow blood flow around a blockage.”

In addition, the promotional flyers that are sent to customers with the Angioprim product contain claims about disease treatment. Examples of such claims include:

- “[D]ietary suppliment [sic] that for over 60 years has been medically tested and proven to reverse heart disease”
- “Angioprim is the best nonsurgical alternative for: Strokes, Angina, Arthritis, and Osteoporosis. You may also have improvements for Diabetes, Kidney, Alzheimer’s & Parkinson disease ...”

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a “new drug” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

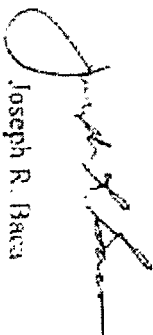
This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice, such as the seizure of illegal products and injunctions against manufacturers and distributors of those products.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur.

If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be addressed to Compliance Officer Kristen L. Moe, 5100 Paint Branch Parkway, HHS-607, College Park, Maryland, 20740-3835.

Sincerely,

A handwritten signature in dark ink, appearing to read "Joseph R. Baca", written in a cursive style.

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition